## REMARKS

Claims 1-26 are pending. Claims 10 and 21 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claims 1-7, 11, 14-19, 22 and 26 stand rejected under 35 U.S.C. §102(b) as being anticipated by Journal Article "Active growth factor delivery from poly(D,L-lactide-coglycolide) foams prepared in supercritical $CO_2$" by David D. Hile *et al.* ("Hile"). Claims 1-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over European Patent Application No. 0405284 ("Greiner") in view of Hile and U.S. Patent No. 5,340,614 to Perman *et al.* ("Perman").

Applicants respectfully traverse the rejections under 35 U.S.C. §112, 35 U.S.C. §102 and 35 U.S.C. §103 for at least the reasons set forth below.

**§112 Rejections Are Overcome**

The Action states that Claims 10 and 21 are indefinite because the term "masking" is not clear as to the intended limitation. Applicants respectfully disagree and submit that the claim language of Claims 10 and 21 is sufficiently clear under §112 and is consistent with the description of embodiments of the invention in Applicants' specification. For example, the paragraph beginning at page 14, line 30 of Applicants' specification states:

> According to embodiments of the present invention, selective removal of toxic or other materials may be accomplished via any of a variety of known masking techniques. For example, a mask may be applied to one or more portions of an intraluminal prosthesis such that toxic materials are removed only from non-masked portions of the polymeric material. Masking techniques are well understood by those skilled in the art and need not be described further herein.

This portion of Applicants' specification clearly states that a mask may be applied to one or more portions of an intraluminal prosthesis such that toxic materials are removed only from non-masked portions of the polymeric material of the intraluminal prosthesis. Moreover, Applicants respectfully submit that those skilled in the art of production of intraluminal prostheses would understand what a "mask" is and how to use such a mask.

Notwithstanding the above, Applicants have amended Claims 10 and 21 as indicated above to further clarify Applicants' invention. Accordingly, Applicants respectfully submit that Claims 10 and 21, read in context of the specification, adequately point out and distinctly claim embodiments of Applicants' invention. As such, the rejections under 35 U.S.C. §112, second paragraph, are overcome.

**§102 Rejections Are Overcome**

A claim is anticipated under 35 U.S.C. §102 if each claimed element is found in a single prior art reference. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991); *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986). There must be no difference between the claimed invention and the reference disclosure, as viewed by an ordinary artisan. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d at 1576.

Applicants' claimed invention is directed to methods of producing biocompatible ***intraluminal prostheses*** wherein densified carbon dioxide is utilized to remove toxic materials from the material of the prostheses and such that the prostheses are suitable for *in vivo* use. For example, the polymeric material of an intraluminal prosthesis is immersed in a densified carbon dioxide composition to absorb toxic materials (*e.g.*, organic solvents, unpolymerized monomers, polymerization catalysts, polymerization initiators, etc.) therefrom. The densified carbon dioxide composition containing the toxic materials is then removed (completely or partially) from the polymeric material and the toxic materials are separated from the carbon dioxide composition by decreasing the density of the carbon dioxide. For example, Applicants' amended Claim 1 recites a method of producing a biocompatible intraluminal prosthesis for *in vivo* use, comprising:

> providing an ***intraluminal prosthesis*** having a portion thereof formed from polymeric material, wherein the polymeric material contains one or more toxic materials;
>
> immersing the polymeric material in a densified carbon dioxide composition such that the ***toxic materials are absorbed by the densified carbon dioxide composition***; and
>
> ***removing the densified carbon dioxide composition containing the toxic materials from the polymeric material, such that the intraluminal prosthesis is suitable for in vivo use.***

Independent Claim 15 contains similar recitations.

Hile describes a method, using supercritical carbon dioxide, for the production of microporous copolymer foams containing encapsulated proteins. Foams generated as aqueous protein emulsions in a polymer-solvent solution are saturated with carbon dioxide at supercritical conditions, and then suddenly supersaturated at ambient conditions causing

bubble nucleation and precipitation of the polymer. Proteins contained in the water phase of the emulsion are encapsulated within the foams, including basic fibroblast growth factor (bFGF).

Applicants have extensively reviewed Hile and cannot find any mention of intraluminal prostheses or, for that matter, any type of device for insertion within a vessel or cavity of a subject. To the contrary, Hile describes synthetic scaffolds for use in forming neocartilage in the shape of ears, tendons, and bladder muscle structures. As such, Hile fails to teach the first recited element (*i.e.*, providing an intraluminal prosthesis) of Applicants' independent Claim 1.

In addition, Hile fails to teach immersing polymeric material in densified carbon dioxide such that toxic materials are ***absorbed*** by the densified carbon dioxide. In contrast, Hile describes removing methylene chloride from the polymeric material by pressurizing a pressure cell with $CO_2$ so as to saturate the polymer with $CO_2$ and extract (*i.e.*, force out) the methylene chloride. Hile does not teach or suggest that the methylene chloride is absorbed by the $CO_2$, as recited in Applicants' independent Claim 1. In addition, Hile specifically states that "residual methylene chloride levels in foams prepared in $CO_2$ were beyond limits imposed by the US Pharmacopeia implying that further solvent removal would be required for these devices prior to in vivo use." (Hile, Page 184). Accordingly, the Hile method alone does not produce a device that is suitable for ***in vivo*** use.

As viewed by the ordinary artisan, there is a great difference between Applicants' invention as claimed in independent Claim 1 and the Hile method. Because Hile does not disclose all of the recited elements of independent Claim 1, Claim 1 and all claims depending therefrom are not anticipated by Hile. For at least the same reasons, independent Claim 15, and all claims depending therefrom, are not anticipated by Hile.

In addition, independent Claim 15 recites a method of producing a biocompatible ***intraluminal prosthesis*** for ***in vivo*** use that includes immersing polymeric material in a densified carbon dioxide composition such that toxic materials from the polymeric material are absorbed by the densified carbon dioxide composition, ***wherein pressure and/or temperature of the densified carbon dioxide composition is adjusted to***

***selectively absorb toxic materials from the polymeric material.*** As discussed above, Hile fails to teach providing an intraluminal prosthesis. In addition, Hile fails to teach immersing polymeric material in densified carbon dioxide such that toxic materials are ***absorbed*** by the densified carbon dioxide. Thus, Hile also fails to teach or suggest selectively absorbing toxic materials from the polymeric material of an intraluminal prosthesis via the adjustment of temperature and/or pressure of densified carbon dioxide.

Because Hile does not disclose all of the recited elements of independent Claim 15, Claim 15 and all claims depending therefrom are not anticipated by Hile. As such, the rejections under 35 U.S.C. §102 are overcome.

**§103 Rejections Are Overcome**

A determination under §103 that an invention would have been obvious to someone of ordinary skill in the art is a conclusion of law based on fact. *Panduit Corp. v. Dennison Mfg. Co.* 810 F.2d 1593, 1 U.S.P.Q.2d 1593 (Fed. Cir. 1987), *cert. denied*, 107 S.Ct. 2187. After the involved facts are determined, the decision maker must then make the legal determination of whether the claimed invention as a whole would have been obvious to a person having ordinary skill in the art at the time the invention was unknown, and just before it was made. *Id.* at 1596. The United States Patent and Trademark Office (USPTO) has the initial burden under § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

To establish a *prima facie* case of obviousness, the prior art reference or references when combined must teach or suggest *all* the recitations of the claims, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. M.P.E.P. § 2143. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. M.P.E.P. § 2143.01(citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990)). As emphasized by the Court of Appeals for the Federal Circuit, to support combining references, evidence of a suggestion, teaching, or motivation to combine must be **clear and particular**, and this requirement for clear and particular evidence is not met by broad and conclusory statements about the teachings of references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). The Court of Appeals for the Federal Circuit also has stated that, to support combining or modifying references, there must be **particular** evidence from the prior art as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000).

Furthermore, as stated by the Federal Circuit with regard to the selection and combination of references:

> This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority. It is improper, in determining

> whether a person of ordinary skill would have been led to this combination of references, simply to "[use] that which the inventor taught against its teacher." W.L. Gore v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Thus the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion....

*In re Sang Su Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002).

The primary reference, Greiner, describes a method of impregnating a catheter, made of polymeric material, with a pharmaceutical. The catheter is immersed into a saturated solution of a pharmaceutical in a solvent. The saturated solution serves as a swelling agent and swells the polymeric material of the catheter. The catheter is contacted with the swelling agent at or near supercritical pressure and temperature of the solvent. The pressure is then reduced from supercritical pressure to release the solvent from the catheter, thereby leaving the pharmaceutical impregnated within the catheter.

Greiner fails to teach or suggest immersing a polymeric material in a densified carbon dioxide composition such that toxic materials are ***absorbed*** by the densified carbon dioxide composition, as recited in Applicants' independent Claims 1 and 15. In fact, the Action appears to concede that Greiner fails to teach or suggest absorbing toxic materials with densified carbon dioxide: "However, Greiner does not focus, although discloses (p.3, col. 3) - methylene chloride - alcohols on removable of toxics." (Action, Page 3).

As discussed above, Hile fails to teach immersing the polymeric material of an ***intraluminal prosthesis*** in densified carbon dioxide such that toxic materials are ***absorbed*** by the densified carbon dioxide. In addition, the method described by Hile does not produce a device that is suitable for ***in vivo*** use. As such, the combination of Greiner and Hile fails to teach or suggest all of the recitations of Applicants' independent Claims 1 and 15.

Perman describes a method of impregnating a polymeric material with an impregnation additive by simultaneously contacting a polymeric material with a carrier liquid and an impregnation additive, exposing the polymeric material, carrier liquid and impregnation additive to a supercritical fluid in a pressure vessel for sufficient time to swell the polymeric material, such that the carrier liquid and impregnation additive can at least partially penetrate the polymeric material, and releasing the pressure in the pressure vessel so

that the carrier liquid diffuses out of the polymeric material, thereby entrapping an amount of the impregnation additive within the polymeric material. The impregnation additive is substantially insoluble in supercritical fluid.

The Action appears to state that Perman teaches tackifier and plasticizer removal: "Perman: the instant process is shown; solvent, (ethanol) tackifier and plasticizer removal by (col. 12) super critical carbon dioxide used with these toxics..." (Action, Page 3). The portion of Perman at Col. 12 that discusses tackifiers and plasticizers is set forth below.

> The fact that the impregnation additives of the present invention are substantially insoluble in the supercritical fluids allows for the impregnation of several different additives into polymer substrates at the same time, without unwanted cross-contamination between the various samples. In addition, this same property, in combination with an inert carrier liquid such as water, will allow for complete recovery of often costly unimpregnated additives after the impregnation process is complete. Further, the use of a carrier liquid will, in many cases, prevent the unwanted extraction of various components, such as plasticizers and tackifiers, from the polymer substrates during the impregnation process. (Perman, Col. 12, Lines 30-42).

Clearly, this passage describes a carrier liquid that ***prevents*** the extraction of plasticizers and tackifiers. Nothing in this passage, or in any other passage in Perman teaches or suggests immersing polymeric material in densified carbon dioxide such that toxic materials are ***absorbed*** by the densified carbon dioxide. To the contrary, Perman teaches away from toxic material absorption.

None of the references cited by the Action, alone or in combination, teach or suggest all of the recitations of Applicants' independent Claims 1 and 15. Accordingly, Applicants respectfully request withdrawal of the present rejections under 35 U.S.C. §103.

**Other Claims Are Independently Patentable**

Claim 4 is patentable by virtue of its dependence on patentable independent Claim 1 as described above. In addition, Claim 4 recites adjusting the pressure and/or temperature of the densified carbon dioxide composition to ***selectively absorb toxic materials*** from polymeric material. None of the references cited in the Action, alone or in combination, teach or suggest adjusting temperature and/or pressure of a densified carbon dioxide composition to selectively absorb toxic materials. As such, Applicants respectfully submit that Claim 4 is independently patentable.

Claim 10 is patentable by virtue of its dependence on patentable independent Claim 1 as described above. In addition, Claim 10 recites ***masking*** one or more portions of the polymeric material prior to immersing the polymeric material in a densified carbon dioxide composition, ***such that toxic materials are absorbed from unmasked portions of the polymeric material***. None of the references cited in the Action, alone or in combination, teach or suggest masking one or more portions of polymeric material prior to immersing the polymeric material in a densified carbon dioxide composition, such that toxic materials are absorbed from unmasked portions of the polymeric material. As such, Applicants respectfully submit that Claim 10 is independently patentable. For at least the same reason, Claim 21 is independently patentable.

In view of the above, it is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,

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